

# Optimising thromboembolic and stroke prevention in pharmacist-managed oral anticoagulothrapy

<b>Submission date</b> 05/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/03/2009	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Lyne Lalonde

### Contact details

Équipe de recherche  
Soins de première ligne  
Centre de santé et de services sociaux de Laval (Cité de la Santé de Laval)  
1755 René-Laennec  
Local D-S145  
Laval  
Canada  
H7M 3L9  
+1 514 343 6111 ext. 5315  
[lyne.lalonde@umontreal.ca](mailto:lyne.lalonde@umontreal.ca)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## **Secondary identifying numbers**

UCT-58955

# **Study information**

## **Scientific Title**

Optimising thromboembolic and stroke prevention: a randomised controlled trial of pharmacist-managed oral anticoagulotherapy

## **Acronym**

PHARMA

## **Study objectives**

Compared to the centralised care model, the integrated care model may be associated with similar anticoagulation control, similar incidence of major haemorrhagic and thromboembolic events and similar patients quality of life. However, the integrated care may represent a more efficient use of the health-care system. It may be less costly.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Cité de la Santé de Laval, Comité d'éthique et de la recherche (conditional approval of the project: 18th December 2001). Full approval as on 12th November 2002 until 11th November 2003; amendments to the protocol made on 16th September 2003. Reapprobation of the project on the following dates:

18th November 2003: reapprobation of the project until 11th November 2004

9th October 2004: reapprobation of the project until 15th September 2005

11th October 2005: reapprobation of the project until 11th November 2006

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Thromboembolism and stroke

## Interventions

A three-year randomised controlled trial (RCT) will be conducted. All patients registering at the PMAS with a first prescription of warfarin for a minimum of six months and who agree to participate (n = 500) will be randomised to the integrated or the centralised PMAS model of care.

Integrated care model: Patients will be monitored by PMAS pharmacists until stabilisation of their international normalised ratio (INR) within their prescribed therapeutic range (six to eight weeks). Thereafter, they will be transferred to their treating physician.

Centralised care model: Patients will be monitored by PMAS for the entire duration of the study.

All patients will be followed for a total of six months. We will monitor the quality of INR control, the incidence of major thromboembolic and haemorrhagic events, the patients health-related quality of life, and direct health-care costs associated with each model of care.

## Intervention Type

Drug

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Warfarin

## Primary outcome measure

The percentage of time spent within the target INR range.

## Secondary outcome measures

1. Incidence and severity of major thromboembolic and haemorrhagic events
2. Health-related quality of life
3. Direct medical-care costs

## Overall study start date

01/01/2001

## Completion date

31/03/2005

## Eligibility

### Key inclusion criteria

1. The patient is referred to the Pharmacy Managed Anticoagulation Service (PMAS) with a prescription of warfarin for at least six months
2. The patient is aged 18 years and older, either sex
3. The patient agrees to go to the Cité de la Santé de Laval, the Centre Hospitalier Ambulatoire Régional de Laval, or one of the four Laval Centre Local de Services Communautaire for blood drawing during participation in the study (six months)
4. The patient lives in the Laval area
5. The patient is able to read and speak French or English
6. The patient agrees to participate in the study and has signed the informed consent form

7. The patient's treating physician has agreed to participate and has signed the informed consent form

8. It is expected that the patient will be transferred to the treating physician

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

500

**Key exclusion criteria**

1. The patient participates to another study
2. The patient is referred to the PMAS for a pre-admission

**Date of first enrolment**

01/01/2001

**Date of final enrolment**

31/03/2005

**Locations****Countries of recruitment**

Canada

**Study participating centre**

Équipe de recherche

Laval

Canada

H7M 3L9

**Sponsor information****Organisation**

Cité de la Santé de Laval (Canada)

**Sponsor details**

University of Montreal  
Laval  
Canada  
H3C 3J7

**Sponsor type**

Government

**Website**

<http://www.cssslaval.qc.ca/>

**ROR**

<https://ror.org/041v96n47>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: UCT-58955)

**Funder Name**

Taro Pharmaceutical Inc. (Canada)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2008		Yes	No

